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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,103	03/14/2007	Kelly M. McNagny	7685-102	4592

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EXAMINER	
HALVORSON, MARK	
ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
01/22/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,103	MCNAGNY ET AL.	
	Examiner	Art Unit	
	Mark Halvorson	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/13/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *3,4,11 and 13-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-10,12 and 34-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/13/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *PTO-Notice to Comply*.

DETAILED ACTION

Claims 1-38 are pending.

Election/Restrictions

Applicant's election with traverse of Group IV in the reply filed on November 13, 2008 is acknowledged. The traversal is on the ground(s) that Groups 1, 3 and 6 all related to the same inventive concept in that they are relate to determining the levels of podocalyxin in cancer. Upon review and reconsideration, the active method steps of Group I claims 1, 2 and 5- 10 are identical to the active method steps of Group IV and thus Group I, claims 1, 2 and 5- 10 are rejoined with claims 12 and 34-38 of Group IV. Applicants also submit that the claims of Groups 3 and 6 related to the combination of podocalyxin and endoglycan levels is narrower than the broad claim to podocalyxin would necessarily retrieve any results related to the more narrow combination, search the search and examination podocalyxin . This is not found persuasive because the invention of selected Group, Group IV is a subcombinatin of the invention of Groups 3 and 6. In addition, a search for a method using podocalyxin would not necessarily include a search for a method using endoglycan. Furthermore, the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicants are reminded that where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 2, 5-10, 12 and 34-38 are pending.

Specification

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below.

Sequences in Figure 5 that are required to be identified by a SEQ ID NO: by 37 CFR 1.821 through 1.825 are not identified by a SEQ ID NO.

In response to this office action, Applicant must comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period. The nature of the non-compliance did not preclude an examination of the elected invention on the merits, the results of which are presented below.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 43, line 10. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The disclosure is objected to because of the following informalities: There are listings for Figure 8(A) and Figure 8(B) with no corresponding Drawings.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2 6-10, 12 and 35-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Xu et al. (US Patent No: 6.613, 515, issued Sept 2, 2003, filed Aug 15, 2000, previously cited).

The claims are drawn to method of detecting cancer, metastatic cancer or progression of cancer in a patient comprising:(a) determining the level of podocalyxin in a sample from the patient; and comparing the level of podocalyxin in the sample to a control sample, wherein increased levels of podocalyxin and as compared to the control indicates that the patient has cancer, wherein determining the level of podocalyxin comprises determining the amount of nucleic acid molecules, wherein the nucleic acid molecules are mRNA, wherein determining the level of podocalyxin comprises determining the amount of protein using an antibody.

Xu et al discloses that podocalyxin is overexpressed in ovarian carcinoma tissues (Table VI) compared to normal ovarian tissue. Xu et al disclose that podocalyxin mRNA may be detected (column 23, line 52 to column 24, line 27) or podocalyxin protein may be detected using an antibody (column 31, line 8 to column 32 line 14).

Claims 1, 2 5-10, 12 and 34-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Erlander et al (US Patent Application Publication No: 2004/0002067, published Jan 1, 2004, filed Dec 21, 2001).

The claims are drawn to method of detecting cancer, metastatic cancer or progression of cancer in a patient comprising:(a) determining the level of podocalyxin in a sample from the patient; and comparing the level of podocalyxin in the sample to a control sample, wherein increased levels of podocalyxin and as compared to the control

indicates that the patient has cancer, wherein the cancer is breast cancer, wherein determining the level of podocalyxin comprises determining the amount of nucleic acid molecules, wherein the nucleic acid molecules are mRNA, wherein determining the level of podocalyxin comprises determining the amount of protein using an antibody.

Erlander et al disclose that podocalyxin is upregulated in ductal carcinoma and invasive ductal breast carcinoma compared to patients with normal and hyperplastic breast tissue. (Example VI. Table 5). Erlander et al disclose that podocalyxin is detected by testing for podocalyxin mRNA (paragraphs 10 and 38) and protein using antibodies (paragraphs 39 and 58).

Summary

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Mark Halvorson/
Examiner, Art Unit 1642